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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,262	04/17/2002	Bruno Criere	017751-030	8894

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,262	CRIERE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12,14-35 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12,14-35 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response and declaration dated 2-21-06 is acknowledged.

Claims 1-7, 9-12, 14-35 and 47 are pending. Claims 8, 13 and 36-46 have been canceled.

Response to Amendment

Upon careful consideration, the finality of the rejection of the last Office action is withdrawn. However, the following new rejection is applied.

Claim Rejections - 35 USC § 103

Claims 1, 4-6, 9-12, 15-21, 23-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,800,079 to Boyer in view of EP 793958 (hereafter EP, submitted on PTO-1449) OR EP in view of Boyer.

Boyer teaches granular fenofibrate compositions comprising fenofibrate wherein each granule comprising an inert core, coated with fenofibrate, and a protective layer. Boyer teaches that the fenofibrate is present in the form of crystalline microparticles of dimensions not greater than 30 microns, and preferably less than 10 microns (abstract). Boyer teaches that the outer protective layer is formed of a substance selected from the group consisting of cellulose polymers, methacrylic polymers, polyvinylpyrrolidone etc., which forms a matrix and the fenofibrate sprayed as a powder is deposited into the polymer matrix (claims). While, Boyer does not specify the percentage of fenofibrate, the example formulation in col. 3 of Boyer shows a high amount of fenofibrate (upto 80% of the formulation). Boyer further teaches incorporation of excipients such as lactose, starch, glucose etc in the composition (claims). Thus, Boyer teaches the

claimed cellulose polymers and excipients and high amounts of fenofibrate, as in claim 1, 4, 9, 10, 15, 18-20 and 28-34. Boyer fails to teach a surfactant in the composition.

EP teaches a fenofibrate composition comprising fenofibrate, surfactant and polyvinylpyrrolidone and other adjuvants, prepared by mixing, granulating and subsequent drying (abstract). EP teaches that the composition does not require a co-micronization of fenofibrate and surfactant and instead can be prepared by mixing fenofibrate particles with PVP and then with surfactants as well as other adjuvants (page 6). With respect to the claimed amount of surfactant, EP teaches a minimum amount of 1.5% of surfactant (page 7), which is within the range of claims 6 and 26. EP also teaches the claimed (claims 5, 25) surfactants such as sodium lauryl sulfate (page 10, 11). EP also teaches fenofibrate as high as 70% to 80% and 10-30% polyvinylpyrrolidone. Further, EP teaches preparing fenofibrate in the form of capsules and hence meets the claimed capsules.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the instant invention to use a surfactant (of EP) in preparing fenofibrate composition of Boyer by mixing the surfactant (without co-micronization with the drug) with micronized fenofibrate because EP suggests such mixing of surfactant reduces the micronization volume of surfactant (as opposed to co-micronizing the drug and surfactant) and results in good bioavailability. Boyer fails to teach the claimed percentage of cellulose polymer, specific viscosity of the cellulosic polymer and the ratios of fenofibrate to polymer. However, Boyer teaches cellulose polymers and PVP as equivalent in forming inert matrix and EP teaches the percentages of PVP in the same range as claimed.

Accordingly, in the absence of any unexpected results, with respect to claimed percentage of cellulose polymer it would have been within the scope of a skilled artisan to employ cellulose (or PVP) as a binding polymer, in compositions comprising high amounts of fenofibrate, surfactants and other adjuvants, at a concentration suggested by EP with an expectation to provide a supporting and binding matrix for fenofibrate. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use cellulose polymer of Boyer in the composition containing high amounts of fenofibrate, adjuvants and surfactant of EP, because Boyer suggests cellulose polymers as equivalent with PVP in providing matrix support and as binders. With respect to the claimed release rate, the burden is shifted to applicants show that the prior art teachings do not provide the claimed release rate.

Claims 2, 3, 7, 14 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer in view of EP 793958 as applied to claims 1, 4-6, 9-12, 15-21 and 23-35 above, and further in view of WO 96/01621 (hereafter WO, submitted on PTO-1449).

The teachings of Boyer and EP have been discussed above. Boyer teaches cellulose polymers in the fenofibrate composition but neither reference teach the specific cellulose polymer of the instant claims.

WO teaches a controlled release composition for insoluble drugs, containing a core around which is coated a drug-containing layer. WO teaches that addition of a hydrophilic polymer in the drug-containing layer, gives favorable mechanical properties

and also a control in the release of the drug upon filling into capsules or sachets (page 4). The process of applying the drug and polymer on the core is described on page 4, lines 20-29. Among the hydrophilic polymers suitable for layering, WO teaches PVP, cellulose derivatives such as hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose, carboxymethylcellulose, methylcellulose etc (page 5, lines 6-12). WO suggests a ratio of active substance to polymer in the range of 10:1 to 1:2 or 5:1 to 1:1, which includes the ratios of instant claims.

While WO does not teach fenofibrate of the instant claims, WO teaches compositions suitable for water insoluble drugs, which includes fenofibrate of Boyer and EP. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use cellulose polymers such as HPMC of WO in the fenofibrate composition of Boyer and EP because WO suggests cellulose polymers such as ethylcellulose and HPMC impart permeability to the coating layer (page 7, lines 18-21). WO further suggests that hydrophilic polymers act as binders and give the composition plastic properties, yield a controlled release that independent of pH. Accordingly, one of an ordinary skill in the art at the time of the instant invention would have expected to increase the plasticity of the fenofibrate composition of Boyer and EP and achieve a pH independent controlled release of fenofibrate with the cellulose polymers in the composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-12, 14-35 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/677,861 (PGPUB 2004/0137055). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims as well as the patented claims are directed to compositions comprising 60% or greater than 60% micronized fenofibrate, surfactant and a binding cellulose derivative. While instant claims recite the composition as containing a neutral granule in which a core is coated with fenofibrate, surfactant and binding cellulose, copending application claim the composition and also claim the instant method of preparing the same. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the instant composition by the method of the copending claims because the copending composition also claims a composition with the same components and accordingly, one of an ordinary skill in the art would have expected the same therapeutic efficacy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7, 9-12, 14-35 and 47 are directed to an invention not patentably distinct from claims 1-45 of commonly assigned 10/677,861. Specifically, as explained above, the copending application also describes a micronized fenofibrate composition employing cellulose binding polymer and a surfactant, wherein the ratios and the percentages of the components are the same. Further, the copending application also teaches the method of preparing the instant composition.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/677,861, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon

the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

Applicant's arguments filed 2-21-06 have been fully considered but they are not persuasive.

The previous rejection of instant claims over Stamm and Curtet references has been withdrawn. Applicants filed a second declaration of George Bobotas, to support the unexpected results provided in the first declaration (dated 10-21-05). With respect to the first declaration, examiner stated that the results were not commensurate with the scope of the claims because the commercial formulations used for comparison does not describe the percentages of fenofibrate and cellulose polymers, and that instant claims differ from the prior art teachings in the percentages of fenofibrate and cellulose polymers. In response, applicants (in the second declaration) now calculated the percentages of fenofibrate of commercial formulations of the instant invention and prior art teachings. It is submitted that in all the examples the fenofibrate percentage was lower than the claimed range, whereas the inventive commercial formulation (ANTARA) comprises 64% fenofibrate and 12% binding cellulose derivative. It is argued that the 130 mg ANTARA capsule formulation results in surprising and unexpected 25.5% increase in bioavailability compared to 200 mg TRICOR capsules, on a per mg

fenofibrate basis. Similarly, applicants argued that the 120 and 144mg ANTARA capsules showed an 20% and 14.7% increased bioavailability respectively, when compared to 160 mg TRICOR tablets of Stamm et al that contained 23% fenofibrate.

The unexpected results presented are not commensurate with the scope of the instant claims for the following reasons:

Instant claim 21 is an interdependent claim, which only recites the ratios of fenofibrate and the cellulose polymer and not the percentages as used in comparative data. Further, applicants provided no information of what are the ratios in the commercial ANTARA formulation and if they are commensurate with those claimed. With respect to the percentages of fenofibrate and cellulose polymers in claim 1, the comparative formulation employs polyvinylpyrrolidone and not cellulose polymers. Thus, the comparative results have two variables – percentages of fenofibrate and two different polymers. Accordingly, the observed increase in bioavailability could be attributed to a difference in the percentages of fenofibrate or dependent on the type of polymer (cellulose versus PVP) used or both, and not solely to the percentage of fenofibrate. However, instant claims are limited to only cellulose polymers and accordingly, the comparative evidence is outside the scope of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615

March 8, 2006